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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,663	04/11/2001	Anthony J. Polak	LFS5044USNP	1850

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Johnson & Johnson
International Patent Law Division
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P.O. Box 1222
New Brunswick, NJ 08903

EXAMINER

YANG, NELSON C

ART UNIT	PAPER NUMBER
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1641

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/832,663	Applicant(s) POLAK ET AL.	
	Examiner Nelson Yang	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 19, 20, 23-26, 28-32, 34-44, 46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 19, 20, 23-26, 28-32, 34-44, 46 and 47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 April 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of claims 1, 4, 5, and 44 is acknowledged and has been entered.
2. Claims 1-17, 19-20, 23-26, 28-32, 34-44, 46, 47 are pending.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-17, 19-20, 23-26, 28-32, 34-44, 46-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claims 1, 44 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the features wherein the labeled analogue is capable of flowing to and from said binding substrate into the void volume, and wherein the quenching dye absorbs the excitation or emission wavelength of the labeled analogue (as disclosed in claim 2, 3) is located within said binding substrate (as disclosed in 13) or within a binder (as disclosed in claim 13), and not capable of flowing into the void volume. Without the labeled analogue being quenched while within the binding substrate, but not within the void volume, the signal of the device would never change, at least not due to the response to the presence of an analyte. Therefore, one of ordinary skill in the art would not have found the device as presently recited in

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claims 1 and 44 to be functional. While it is noted that the claims are read in light of the specification, limitations in the specification may not be read into the claims.

6. The remaining claims are indefinite due to their independence on an indefinite claim. It is noted while some of the claims do disclose some of the missing essential features, none disclose all the missing essential features.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 44 rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The features wherein the labeled analogue is capable of flowing to and from said binding substrate into the void volume, and wherein the quenching dye absorbs the excitation or emission wavelength of the labeled analogue (as disclosed in claim 2, 3) is located within said binding substrate (as disclosed in 13) or within a binder (as disclosed in claim 13), and not capable of flowing into the void volume are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Without the labeled analogue being quenched while within the binding substrate, but not within the void volume, the signal of the device would never change, at least not due to the response to the presence of an analyte. Therefore, one of ordinary skill in the art would not have found the device as presently recited in claims 1 and 44

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to be functional. While it is noted that the claims are read in light of the specification, limitations in the specification may not be read into the claims.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-17, 19-20, 23-26, 29, 34-44, 46, 47 are rejected under 35 U.S.C. 103(a) as being anticipated by Schultz [US 6,256,522] in view of Krauth [US 4,954,435] and further in view of Vo-Dinh [US 5,864,397] and further in view of Mills et al. [US 5,232,712].

With respect to claim 1-4, 7-8, 19, 20, 23-26, 29, Schultz teaches a receptor material, Concanavalin A covalently attached to Rhodamine dye molecules, analog analyte comprising dextran covalently attached to fluorescein dye molecules located within a transparent capsule comprising a semi-permeable membrane comprising cellulose or polysulfone (column 10, lines 21-37, claim 1). Schultz further teaches a pH indicator located within the capsule (column 11, lines 1-5, claim 1), as well as a second dye of a second wavelength different from the first wavelength (column 13, lines 15-20). The rhodamine quenches emission fluorescence from the fluorescein (column 10, lines 38-45). With respect to claim 4, the receptor material may be immobilized to a gel such as polyethylene glycol within the chamber (column 8, lines 11-27). Schultz fails to specifically teach using the pH indicator or a second dye as a reference dye, or

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that the binding substrate has a molecular imprint of the analyte, and also fails to teach that the device is seamless.

Krauth, however, teaches that in fluorescence assays, using a ratio of light signals, one signal being the reporter signal, and the other being the reference signal, provides a correction mechanism for obviating such variables such as fluctuation in the lamp output, variation in tube position, diameter, or optical quality (column 3, lines 50-61).

Vo-Dinh further teaches the use of a molecular imprint material designed to concentrate specific compounds of interest for improved sensitivity (column 6, lines 63-65).

Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to use the pH indicator as a reference dye as suggested by Krauth in the device of Schultz et al., in order to obviate such variables such as fluctuation in the lamp output, variation in tube position, diameter, or optical quality when detecting the presence of analytes. It would have further been obvious to use a molecular imprint material, as suggested by Vo-Dinh, in the device of Schultz, in order to concentrate specific compounds of interest for improved sensitivity.

Mills et al., however, teach extrusion systems for fabrication of implants and encapsulation systems that provides a seamless closure (column 1, lines 30-39, column 5, lines 9-20)).

Therefore, one of ordinary skill in the art at the time of the invention would have been motivated to provide a seamless membrane encapsulating the device of Schultz et al., as suggested by Mills et al., in order to reduce immune response, and provide a protective barrier against immunogens, while removing the weakness of a seam that could potentially leak or burst.

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11. With respect to claims 5-6, although neither Schultz nor Krauth teaches a reference covalently bonded to the membrane or in the membrane, it would have been obvious to one having ordinary skill at the time was made to have the reference covalently bonded to the membrane or in the membrane, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, USPQ 70.

12. With respect to claims 9-12, Schultz teaches that the analyte and receptor may bind to form an analyte-receptor complex (column 6, lines 40-50) and comprise dextran (column 10, lines 20-37).

13. With respect to claims 13-17, Schultz teaches that the receptor material can be immobilized to a gel such as polyacrylamide (column 8, lines 20-28). Schultz further teaches that rhodamine dye molecules can be attached to the receptor material for quenching fluorescence (column 10, lines 25-45).

14. With respect to claims 34-36, Schultz teaches that the semi-permeable membrane comprising cellulose or polysulfone (column 10, lines 21-37, claim 1)

15. With respect to claim 37, Schultz teaches that the analyte-permeable membrane may also have a reflector comprising metallic particles immobilized on the surface of an ultrafiltration membrane (column 10, lines 1-10).

16. With respect to claims 38-39, Schultz teaches that the analyte being measured is glucose (column 10, line 25).

17. With respect to claims 40-43, while Schultz do not teach what the ratio of the empty space encapsulated by the capsule to a volume occupied by the binding substrate is, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the

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optimum or workable ranged involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Furthermore, since applicant has not discussed any unexpected improvements or results using ratios between 0.05 and 5, between 0.5 and 3, or 1, it would have been obvious to a person of ordinary skill in the art to have used ratios between 0.05 and 5, between 0.5 and 3, or 1 through normal optimization techniques.

18. With respect to claims 44, 46, 47, the sensor unit may be placed underneath the skin (column 7, lines 27-36), illuminated with a laser (column 7, lines 38-45), and measuring absorption of light, including ultraviolet, visible or infrared (column 7, lines 15-25).

19. Claims 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz [US 6,256,522] in view of Krauth [US 4,954,435] and Vo-Dinh [US 5,864,397] and in view of Mills et al. [US 5,232,712], as applied to claim 1 above, and further in view of Ferri et al. [Ferri et al., Direct eye visualization of fluorescence for immunocytochemistry and in situ hybridization, 2000, J Hist Cytochem, 48(3), 437-444]

The combination of Schultz, Vo-Dinh, Krauth and Dionne et al. teach the use of a reference, as discussed above, but do not teach the use of cyanine dyes such as Cy5.

Ferri et al., however, teach that Cy5 provides a distinct fluorescent signal that can easily be separated from that of many other fluorochromes (p.437, col.1). Ferri et al. further teach that a distinct advantage of Cy5 is the low autofluorescence found in many cells and tissues in the above wavelength range (p.437, col.1).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use Cy5 as a reference in the device of Schultz, Krauth et al., Vo-Dinh, and Ketterl et al. as suggested by Ferri et al., as one would have been motivated to provide a distinct

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fluorescent signal that can be easily separated from other fluorochromes by using Cy5 as a reference.

20. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schultz [US 6,256,522] in view of Krauth [US 4,954,435] and Vo-Dinh [US 5,864,397] and in view of Mills et al. [US 5,232,712], as applied to claim 1 above, and further in view of Bruchez et al. [US 6,274,323].

Schultz, Vo-Dinh, Krauth, and Dionne et al. teach the use of a reference, as discussed above, but fail to teach the use of quantum dots as a reference.

Bruchez et al., however, teach that semiconductor nanocrystals may be used to detect or track a single target, and can be used to in a variety of assays where other, less reliable, labeling methods have typically been used, including fluorescence microscopy, histology, cytology pathology, flow cytometry, FISH, signal amplification assays, DNA and protein sequencing, immunoassays, immunohistochemical analysis, homogeneous assays, high throughput screening, and the like (column 16, lines 58-67).

Therefore it would have been obvious to use semiconductor nanocrystals, or quantum dots, instead of a label as a reference in the device of Schultz, Krauth, Vo-Dinh, and Ketterl et al. as suggested by Bruchez et al., in order to provide a more reliable labeling method.

Response to Arguments

21. Applicant's arguments with respect to claims 1-17, 19-20, 23-26, 28-32, 34-44, 46, 47 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

22. No claims are allowed.
23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571)272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

24. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nelson Yang/
Patent Examiner
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